

REMARKS

Claims 1-26 are pending in the application. Claims 1-26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. 5,464,416 to Steckel in view of U.S. Pat. No. 5,632,753 to Loeser. The applicant respectfully traverses the Examiner's rejection for the reasons set forth below.

According to the *PTO Examination Guidelines*¹, in light of *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. ___, 82 USPQ2d at 1396 (2007) the proper analysis required to reject the claims on obviousness grounds requires:

(1) **a finding that the prior art included each element claimed**, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference;

(2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that **in combination, each element merely would have performed the same function as it did separately**;

(3) a finding that **one of ordinary skill in the art would have recognized that the results of the combination were predictable**; and

(4) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

Independent claim 1 is directed to a surgical clip that includes:

a first arm portion having a tip and an opposite end;
a second arm portion having a first end and an opposite end;
a retainer extending from said first end of said second arm portion, said retainer extending **beyond said tip of said first arm portion and substantially parallel**

¹ *Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.*, Oct. 10, 2007, [Docket No.: PTO-P-2007-0031].

to said **first arm** portion and being **deformably bendable** and having a tissue piercing tip; and

a bridge portion connecting said opposite ends of said first and second arm portions,

wherein said first and second arm portions and said bridge portion are in a generally U-shaped configuration, and **said retainer is adapted to be plastically deformed toward said first arm portion** and about or adjacent said tip of said first arm portion.

In view of the above, applicant respectfully submits that claim 1 is not obvious under 35 U.S.C. § 103(a) for the following reasons.

First, Applicant submits that the cited prior art does not include all of the elements of claim 1. Claim 1 requires that the retainer extend from the second arm **beyond the tip of the first arm** in a direction **substantially parallel** to the first arm. Claim 1 also requires that the retainer be **adapted to be plastically deformed toward the first arm**. The Examiner admits that Steckel does not disclose a retainer that extends substantially parallel to the first arm and deforms to engage the second arm. In fact, Steckel discloses a resilient hook (which the Examiner purports to be a retainer) that does not extend beyond the tip of the first arm, is not substantially parallel to the first arm, and is not adapted to be plastically deformed toward the first arm.

Loeser does not even disclose a second arm, let alone a retainer extending from a second arm beyond the tip of the first arm in a direction substantially parallel to, and adapted to be plastically deformed toward, the first arm. The Examiner states that Loeser discloses a surgical clip. However, Loeser, as shown in Figures 1 and 3, discloses a

ligature or suture (col. 1, line 48 et seq.; col. 3, line 43) that is designed to cinch a vessel by means of an elongated flexible base structure 22 that interacts with a latch collar 36. The latch collar 36 secures a needle end 28 of the base structure 22 by means of nodes 24 operably disposed on and situated perpendicular to the elongated base structure 22. The base structure 22 of the suture is designed to be a highly flexible continuous ligature capable of bending into any number of configurations to form a stitch or cinch around a vessel or fallopian tube. The suture disclosed in Loeser is clearly not plastically deformable because it needs to be "flexible enough to be stitched," and does not have the ability to undergo permanent deformation. The ligature or suture disclosed in Loeser is designed to not retain its shape absent external forces acting on it, and thus is not plastically deformable. Therefore, neither Steckel nor Loeser shows a retainer extending from a second arm in a direction substantially parallel to the first arm, or a retainer that is adapted to be plastically deformed toward the first arm.

Second, Applicant submits that the "applicable" elements disclosed in Loeser would not perform the same functions when used in combination with Steckel. Steckel discloses a resilient clip formed in a normally open configuration. The clip is adapted to grasp, compress, and clamp tissue, and maintains a closed configuration through the use of a hook member (the purported "retainer") that is lockably received by a recess defined in an opposing arm. In order to facilitate the above functions of the Steckel clip, the Steckel hook member is angled inward (Fig. 1) or orthogonal (Fig. 10) relative to the arms of the clip while the clip is closed. In addition, the Steckel retainer is required to pierce through tissue, lockably connect with a recess on an opposite arm as the clip is

closed, and hold the clip in a closed configuration over the compressed tissue despite both the clip's natural bias and the internal pressure of the tissue, both of which would, absent the retainer, force the clip to an open configuration. These functional requirements of the Steckel retainer are very different from any function or retaining elements disclosed in Loeser.

In fact, it is not clear what the Examiner refers to as the "retainer" in Loeser. The Loeser ligature is flexible enough to be stitched, designed to accommodate a variety of shapes, and has a needle end and nodes disposed on the ligature near the needle end orthogonal to the ligature. The Loeser ligature is designed to be manually pulled or pushed at one end through an area of tissue and then pulled or pushed through the latch collar until it is cinched to a desired pressure around a vessel or fallopian tube. The nodes on the Loeser ligature might be considered to "retain" the ligature to the extent that they prevent the ligature from slipping relative to the latch collar. But the nodes do not connect arms on the ligature or resist a change in the ligature's shape toward an open configuration. Instead, the Loeser ligature must be *flexible enough to be stitched to facilitate a change in the overall structure of the device so that the stitch can be cinched*. Therefore, the retaining elements of Loeser do not operate to perform the functions of the Steckel retainer.

Third, Applicant submits that one of ordinary skill in the art would not have recognized that the results of the combination of Steckel and Loeser were predictable. Steckel and Loeser teach away from each other. The Steckel clip needs to function as a

jaw to grasp and compress the tissue. As such, a Steckel hook member extending outward from the edge of one jaw in a direction substantially parallel to the other jaw would likely impede the clip's approach to the tissue. Moreover, given that the Steckel locking mechanism comprised of the hook member and corresponding recess is critical to the function of the Steckel clip, extending the Steckel retainer in substantially the same direction as the arm to which it attaches would direct the retainer away from the recess rather than towards it as the clip is closed, thus precluding or inhibiting its function. Steckel thus teaches away from using a retainer substantially parallel to either of the arms of the clip.

Loeser discloses a ligature or suture that is "flexible enough to be stitched" and cinched, not a surgical clip as the Examiner has purported. The flexible base structure of the suture disclosed in Loeser is drawn through tissue, looped through the latch collar, and pulled at one end to cinch the wound. One skilled in the art would not be motivated to combine the rigid surgical clip of Steckel, which requires a short resilient hook directed toward an opposing arm, with the highly flexible suture disclosed by Loeser, nor is there any teaching or suggestion to do so.

Notwithstanding the above, even if, as the Examiner has proposed, the hook member of Steckel were modified in light of Loeser and operated to somehow lock the arms of the clip together and facilitate the gripping and compressing action of the clip despite extending substantially parallel to the second arm portion, and even if the hook member could further be "deformed" 180 degrees, such a hypothetical clip would still not

be adapted to plastically deform toward and adjacent to the first arm portion. Neither Loeser nor Steckel teaches or suggests a retainer that plastically deforms toward or adjacent the first arm portion. Instead, Steckel discloses a resilient retainer while Loeser discloses a highly flexible ligature. Therefore, both Steckel and Loeser teach away from each other and from Applicant's invention. Moreover, even if the Steckel hook member were plastically deformable and designed to deform under the pressure of clamping down on tissue, it could miss the recess 24 in the closed orientation, which would preclude the Steckel clip's operation.

It is also important to note that the overall operation of Applicant's invention as claimed by claim 1 is very different from that disclosed in both Steckel and Loeser. Steckel requires that the hook member catch on the opposing arm of the clip. Applicant's invention does not. As discussed above, the leg members 12, 14 in Steckel are held in position around the clamped tissue by the hook member 22. Absent the hook, the tissue would push the leg members 12, 14 back to an open configuration because the legs are hinged about the bridge and biased toward an open configuration. By contrast, the elements of applicant's claim 1 do not require that the retainer "engage" the second arm as the examiner states, but rather, that the retainer be plastically deformable about or adjacent to the tip of the first arm. Applicant's clip does function to hold tissue in compressed form, but Applicant's retainer does not function to hold the arms of the clip in the closed position around the tissue. Rather, Applicant's retainer helps to prevent the clip from backing off of the flesh or tissue. Thus, the overall operation of Applicant's

invention is different from that disclosed in Steckel, Loeser, or any hypothetical combination of the two.

For the above reasons, Applicant respectfully submits that claim 1 is patentable over the cited art.

Independent claims 5, 9, 13 and 17 are patentable over the cited prior art for many of the same reasons that claim 1 is patentable over the cited art, and claims 9, 13 and 17 are also patentable for reciting additional features that are neither taught nor suggested by the prior art. For example, independent claim 5 includes the limitation that the retainer be plastically deformable and extend from the first arm substantially parallel to the second arm. This is not taught or suggested by Steckel or Loeser. Independent claim 9 includes the limitation that the retainer extend from the second arm beyond the tip of the first arm, and that the clip have an original configuration in which the retainer is substantially parallel to the first and second arms, and a second applied configuration in which a tip of the retainer is bent around or adjacent to the first arm. This is not taught or suggested by Steckel or Loeser. Independent claims 13 and 17 include the limitation that the retainer be plastically deformable, as well as the added limitation that the first and second arm portions and bridge portion be relatively stiff. This is not taught or suggested by Steckel or Loeser. Claim 17 also includes the limitation that the surgical clip include a plurality of retainers. The Examiner states that including a plurality of retainers would have been obvious to one skilled in the art, but provides no basis or evidence for this assertion. The hook disclosed in Steckel, which the Examiner has referred to as the

retainer, simply latches the legs together. When the clip is closed, the hook is disposed inside the recess and no longer needs to pierce the tissue. Therefore, Steckel does not disclose multiple retainers or give rise to any incentive for providing them. By contrast, applicant's retainer pierces the tissue during and after the clip is mounted thereon, which prevents the clip from backing off of the tissue.

For the reasons set forth above, Applicant submits that the limitations set forth in claims 1-20 are not disclosed by the prior art. Furthermore, and as discussed above, there is no reason to believe that one skilled in the art would think to combine the suture disclosed in Loeser with the clip disclosed in Steckel. Moreover, Loeser and Steckel both teach away from applicant's claims, and combining them would not produce the claimed limitations.

Independent claim 21 is directed to a method of applying a surgical clip to tissue that includes:

providing a surgical clip having,
a first arm portion having a tip and a first opposite end,
a second arm portion having a retainer extending therefrom **in substantially the same direction as said second arm** and a second opposite end, and
a bridge portion connecting the first and second opposite ends;
providing the first and second arm portions about the tissue; and
folding the retainer about the tip of the first arm.

In rejecting claim 21, the Examiner admits that Steckel does not disclose a retainer extending in substantially the same direction as the second arm, but contends that Loeser contains this feature. The Examiner further states that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the retainer in

Steckel to extend in substantially the same direction as the second arm to "increase the versatility of the device" as taught by Loeser. However, as discussed above, Loeser does not disclose a clip having two arms with a retainer extending in substantially the same direction as one of the arms. Instead, Loeser discloses a continuous ligature designed to form a suture, not a clip having two arms. Given that the retainer in Steckel is lockably received by a recess disposed on an opposing arm, and that such locking is critical to the function of the Steckel clip, it would not be obvious to extend the Steckel retainer in substantially the same direction as the arm to which it attaches because doing so would direct the retainer away from the recess rather than towards it as the clip is closed. Also, neither Steckel nor Loeser discloses the limitation of **folding** the retainer about the tip of the first arm.

Claims 22-26 are patentable over the cited prior art for those reasons advanced above with respect to claim 21, from which they respectfully depend, and for reciting additional features that are neither taught nor suggested by the prior art. For example, claim 22 includes the limitation of compressing the tissue prior to providing the first and second arm portions about the tissue. In Steckel, as the jaws of the clip are used to compress the tissue, the compression is performed simultaneously as the clip is applied to the tissue. Loeser does not compress the tissue prior to applying the suture. Rather, it is the suture itself that compresses the tissue as it is cinched. Thus neither Steckel, Loeser, nor the combination of the two contain the elements claimed in claim 22.

For the reasons set forth above, applicant submits that the limitations set forth in claims 21-26 are not disclosed, suggested, or taught by the prior art.

In light of all of the above, it is submitted that the claims are in order for allowance, and prompt allowance is earnestly requested. Should any issues remain outstanding, the Examiner is invited to call the undersigned attorney of record so that the case may proceed expeditiously to allowance.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'David S. Jacobson', with a stylized flourish at the end.

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